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10/584,159	08/22/2008	Hirotochi Adachi	Q125296	5061

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EXAMINER
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ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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11/21/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@sughrue.com  
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## Office Action Summary

Application No.

10/584,159

Applicant(s)

ADACHI ET AL.

Examiner

MICHAEL J. ANDERSON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-23 is/are pending in the application.
- 5a) Of the above claim(s) 1-3,6-8,15 and 16 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 4,5,9-14 and 17-23 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 22 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/18/2006</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 1-3, 6-8, 15-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/28/2011.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

The references cited 8/18/2006 have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08 in compliance with 37 CFR 1.98(a)(1).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-5, 9-14, 17-18 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by Konno (US 4,842,577).

With regards to claim 4, Konno discloses (figure 4; column 2, lines 29-34) an iontophoresis device activated in use comprising: a drug-containing layer (1) containing a dry drug (column 2, lines 35-68, the medicament layer is kneaded into a layer of material and can be in a dry state); an absorber (2) disposed on said drug-containing layer and formed of a material capable of absorbing a liquid (column 4, lines 5-19); a wall material (3) disposed around said absorber, having an adhesive layer (bottom of 3 is an adhesive layer) on the undersurface thereof; a support (5) disposed on said absorber and said wall material, having an opening (figure 4; column 4, lines 33-44; center of 5 contains an opening cover by thin foil) in the central portion thereof; an electrode (4) disposed on the undersurface of said support; a diaphragm (figure 4; column 4, lines 33-44; center of 5 contains an opening cover by thin foil diaphragm) disposed on said support; and a dissolution liquid reservoir (figure 4, 6 is in the reservoir) disposed on said diaphragm, retaining a dissolution liquid (6) for dissolving said drug between said diaphragm and itself, and having a protruding portion (column 4, lines 33-44, "V" shape at the top center portion of 6 is collapsed into the foil at the center of 5) for destroying said diaphragm by pressing force.

With regards to claim 5, Konno discloses the iontophoresis device activated in use according to claim 4, further comprising a liner (column 4, lines 62-65, a release liner is used in a seal stated and its shape would be concave when used with the device of figure 4) on the undersurface of both said drug-containing layer and said adhesive layer, wherein said liner has a concave portion opposed to said drug-containing layer.

With regards to claim 9, Konno discloses (figure 4) the iontophoresis device activated in use according to claim 4, wherein the dissolution liquid-contacting portion of said diaphragm has an oval form, and that the protruding portion (column 4, lines 33-44, “V” shape at the top center portion of electrolyte capsule (capsule has an oval shape) 6 is collapsed into the foil at the center of 5, and can be have different shapes as a design choice without deviating from the scope of the invention) of said dissolution liquid reservoir has a linear apical portion that extends in the longitudinal direction of said oval form.

With regards to claim 10, Konno discloses the iontophoresis device activated in use according to claim 9, wherein assuming that the length of said linear apical portion is given by  $L1$  and the length of the dissolution liquid-contacting portion of said diaphragm in the longitudinal direction is given by  $L2$ , the relationship of  $0.1 \times L2 \leq L1 \leq 0.5 \times L2$  is satisfied (column 4, lines 33-44, “V” shape at the top center portion of 6 is collapsed into the foil at the center of 5 and can be assumed to have many longitudinal lengths as a design choice).

With regards to claim 11, Konno discloses the iontophoresis device activated in use according to claim 4, wherein the dissolution liquid-contacting portion of said diaphragm has a round form, and that the protruding portion of said dissolution liquid reservoir has cross-shape apical portions (column 4, lines 33-44, “V” shape at the top center portion of 6 is collapsed into the foil at the center of 5, and can be have different shapes as a design choice without deviating from the scope of the invention).

With regards to claim 12, Konno discloses the iontophoresis device activated in use according to claim 10, wherein assuming that the lengths of said cross-shape apical portions are given by  $L_{10}$  and  $L_{11}$  and the diameter of the dissolution liquid-contacting portion of said diaphragm is given by  $L_2$ , the relationships of  $0.1 \times L_2 \leq L_{10} \leq 0.5 \times L_2$  and/or  $0.1 \times L_2 \leq L_{11} \leq 0.5 \times L_2$  are satisfied (column 4, lines 33-44, “V” shape at the top center portion of 6 is collapsed into the foil at the center of 5 and can be assumed to have many longitudinal lengths and shapes as a design choice without deviating from the scope of the invention).

With regards to claim 13, Konno discloses the iontophoresis device activated in use according to claim 4, wherein the peripheral portion of the opening of said support is dented to said absorber side more than the rest of said support (column 4, lines 33-44, “V” shape at the top center portion of 6 is collapsed into the foil at the center of 5 which provides for such a dented feature).

With regards to claim 14, Konno discloses the iontophoresis device activated in use according to claim 4, wherein said support is inclined so that the opening is closer toward said absorber side than the peripheral portion of said support (figure 4, support 5 has an incline at the peripheral portion).

With regards to claim 17, Konno discloses the iontophoresis device activated in use according to claim 4, wherein said dissolution liquid reservoir is formed by processing of a sheet material (electrolyte capsule 6 of figure 4), and in that said sheet material has a water vapor permeability of  $0.22 \text{ g/m}^2 \cdot 24 \text{ hr}$  or less (electrolyte capsule 6 of figure 4, holds its contains until used).

With regards to claim 18, Konno discloses the iontophoresis device activated in use according to claim 17, wherein said sheet material has a thickness between about 250 and about 350  $\mu\text{m}$  (figure 4, column 4, lines 29-32 discloses layer 3 to be 1 to 5 mm and the capsule 6 is about 0.25 to 0.35 mm in comparison size).

With regards to claim 23, Konno discloses the iontophoresis device activated in use according to claim 4, wherein said diaphragm is an aluminum foil (figure 4; column 4, lines 33-44; center of 5 contains an opening cover by thin foil diaphragm).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konno (US 4,842,577) in view of Takahashi (US 6,329,465 B1).

With regards to claim 19, Konno discloses the iontophoresis device activated in use according to claim 17. However, Konno does not explicitly disclose wherein said sheet material comprises a cyclic polyolefin copolymer film. Takahashi teaches (abstract; column 39, lines 38-61) the use of sheet material comprising a cyclic polyolefin copolymer film. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the capsule 6 of Konno as disclosed by Takahashi for providing a sealant layer.

With regards to claim 20, Konno discloses the iontophoresis device activated in use according to claim 17. However, Konno does not explicitly disclose wherein said sheet material is a laminated film consisting of a cyclic polyolefin copolymer film and a polyolefin film. Takahashi teaches (abstract; column 39, lines 7-61, the layers include olefin polymers) the use of sheet material comprising a cyclic polyolefin copolymer film and a polyolefin film. Therefore, it would have been obvious to a person of ordinary skill



in the art at the time the invention was made to modify the capsule 6 of Konno as disclosed by Takahashi for providing a sealant layer.

With regards to claim 21, Konno discloses the iontophoresis device activated in use according to claim 17. However, Konno does not explicitly disclose wherein said sheet material comprises a fluorocarbon resin film. Takahashi teaches (abstract; column 78, lines 28-35), the layers include fluorocarbon) the use of sheet material comprising a fluorocarbon resin film. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the capsule 6 of Konno as disclosed by Takahashi for providing a sealant layer.

With regards to claim 22, Konno discloses the iontophoresis device activated in use according to claim 17. However, Konno does not explicitly disclose wherein said sheet material is a laminated film consisting of a fluorocarbon resin film and a polyolefin film. Takahashi teaches (abstract; column 39, lines 7-61, the layers include olefin polymers; column 78, lines 28-35, the layers include fluorocarbon) the use of sheet material comprising a fluorocarbon resin film and a polyolefin film. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the capsule 6 of Konno as disclosed by Takahashi for providing a sealant layer.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-5, 9-14, 17-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/584,172 in view of Konno (US 4,842,577) and Takahashi (6,329,465 B1). With regards to claims 4-5, 9-14, 17-18 and 23, Application No.

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10/584,172 claims an iontophoresis device activated in use comprising: an absorber disposed on said drug-containing layer and formed of a material capable of absorbing a liquid and Konno teaches (column 4, lines 62-68), a dry absorbent layer containing electrolyte and Takahashi teaches (abstract; column 39, lines 7-61), the layers include olefin polymers; (column 78, lines 28-35), the layers include fluorocarbon. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the device of Application No. 10/584,172 with the capsule 6 of Konno as disclosed by Takahashi for providing a sealant layer.

This is a provisional obviousness-type double patenting rejection.

### ***Response to Amendment***

The present communication responds to the Amendment of 9/28/2011. By this communication, claims 9, 11, 13, 14, 16, 17 and 23 were amended. The amendments did not add new matter. Claims 1-23 are pending with claim 1-3, 7-8 and 15-16 withdrawn. The rejection(s) are as stated.

### ***Conclusion***

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL J ANDERSON/  
Examiner  
Art Unit 3767

MJA  
11/11/2011

/(Jackie) Tan-Uyen T. Ho/  
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